**Validation** is a process of establishing documentary evidence demonstrating that a procedure, process, or activity carried out in production or testing maintains the desired level of compliance at all stages. In Pharma Industry, it is very important apart from final testing and compliance of product with standard that the process adapted to produce itself must assure that process will consistently produce the expected results.Here the desired results are established in terms of specifications for outcome of the process. Qualification of systems and equipment is therefore a part of process of validation. It is a requirement of food and drug, pharmaceutical regulating agencies like FDA's good manufacturing practices guidelines

Some of the technical terms in validations which are very important to know:

**Actual Result** – What a system does when an action is performed

**Deliverable** – A tangible or intangible object produced because of project execution, as part of an obligation. In validation projects, deliverables are usually documents.

**Deviation** – When a system does not act as expected

**End-User** – A person who uses the validated system

**Expected Result** – What a system should do when an action is performed

**Protocol** – A collection of Test Cases, used to document the testing of a system

**Qualification** – A testing protocol which designates that a system meets a collection of requirements. An Installation Qualification ensures that a system has been properly installed. An Operational Qualification demonstrates that a system functions as expected in a controlled environment. A Performance Qualification verifies that a system works under real-life conditions.

**Quality Assurance** – Members of the organization who are tasked with ensuring the quality of materials produced at that organization. GxP organizations are required to have robust and independent Quality Assurance operations. Depending on the organization, this group may be titled Quality Control or Quality Organization; other organizations have multiple groups dedicated to quality with their own distinct missions.

**Requirement** – Something a system must be able to do

**Retrospective Validation** – Validation of an existing system. Retrospective validations are usually performed in response to a new need for a system to be compliant or an identified gap in GxP compliance.

**Specification** – A document outlining the requirements for a system. Specifications are usually sub-divided into User Requirements Specifications, Functional Requirements, and Design Specifications.

**System** – Object or process undergoing validation. In these pages, system is intended to be a generic term, meaning computer system, equipment, method or process to be validated.

**System Owner** – The individual who is ultimately responsible for a system

**Test Case** – A documented procedure, used to test that a system meets a particular requirement or collection of requirements

**Test Plan** – A general testing methodology established to ensure that a system meets requirements. A Test Plan can also refer to the collection of protocols or qualifications used to test and document that a system meets requirements.

**Test Step** – An individual line of a Test Case. Each Test Step should include instructions, an expected result, and an actual result.

**Traceability** – The ability to ensure that requirements outlined in the specifications have been tested. This is usually recorded in a Requirements Traceability Matrix.

**Validation** – A documented process, testing a system to demonstrate and ensure its accuracy, reliability, and consistent intended performance

**Validation Package** – A collection of documents produced during a validation project

Here some of the acronyms:

**CC** – Change Control  
**DS** – Design Specification  
**FAT** – Factory Acceptance Testing  
**FS** – Functional Specification  
**FRS** – Functional Requirement Specification (See Functional Specification)  
**GCP** – Good Clinical Practice, a collection of quality guidelines for clinical operations  
**GLP** – Good Laboratory Practice, a collection of quality guidelines for pharmaceutical laboratory operations  
**GMP** – Good Manufacturing Practice, a collection of quality guidelines for pharmaceutical manufacturing operations  
**GxP** – An abbreviation combining GCP, GLP, and GMP. Sometimes also called cGxP, Current Good Practices  
**IQ** – Installation Qualification  
**IOPQ** – Installation/Operational/Performance Qualification  
**IOQ** – Installation/Operational Qualification  
**PQ** – Performance Qualification  
**OPQ** – Operational/Performance Qualification  
**OQ** – Operational Qualification  
**RTM** – Requirement Traceability Matrix  
**SAT** – Site Acceptance Testing  
**SDS** – Software Design Specification (See Design Specification)  
**Spec** – Specification  
**TM** – Traceability Matrix  
**UAT** – User Acceptance Testing  
**URS** – User Requirement Specification  
**VMP** – Validation Master Plan  
**VP** – Validation Plan